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Novel intervention strategies for schistosomiasis elimination in Zanzibar

Submission date
21/01/2020

Recruitment status
No longer recruiting

Registration date
11/02/2020

Overall study status
Completed

Last Edited
04/02/2026

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol
Background and study aims
Urogenital schistosomiasis is a parasitic disease caused by flatworms such as Schistosoma haematobium that are released by freshwater snails. In line with the goals set by the World Health Organization for 2020 and 2030, the Zanzibar government is committed to eliminate urogenital schistosomiasis as a public health problem and to interrupt Schistosoma haematobium transmission from Zanzibar in the next years. Intensified mass drug administration (MDA) with biannual community-wide and school-based treatments started in 2012, and was complemented with additional interventions (snail control and behaviour change) within a trial conducted from 2012 to 2017. During this trial, several challenges on the last mile towards schistosomiasis elimination were identified. This study will address some of the identified challenges, including persistent hotspots of transmission, recurrence of infection, and diagnostics, and investigate new tools and strategies for breaking schistosomiasis transmission. The main aim of the study is to test the sensitivity of an adaptive surveillance-response system for its ability to detect S. haematobium infected individuals in low-risk areas to trigger an appropriate intervention response to avoid recurrence of infection.
The other aims are to reveal the performance of the surveillance-response system in terms of overall feasibility, timeliness, and acceptability. Moreover, the impact of intervention packages in hotspots and low-risk areas will be measured, the treatment coverage of (focal) MDA or test-and-treat in infected and healthy individuals will be assessed, and the performance of the diagnostic approaches used will be assessed.

Who can participate?
The study will be implemented in the North of Pemba island for 3.5 years. A cross-sectional baseline and three annual follow-up surveys will be conducted in schools and communities from 2020 to 2023. Schoolchildren, male and female, from nursery till grade 7 will be invited to participate in the school-based surveys. Participants of all sexes aged 4 years and older will be eligible to participate in the community-based surveys. Moreover, all community members aged 4 years and older will be eligible to be tested for S. haematobium infection during the surveillance activities implemented throughout the study years in low-risk shehias.

What does the study involve?
Participants will be tested for S. haematobium infection and blood in their urine. Participants will

be invited to answer a questionnaire about their past anti-schistosomal treatments and behaviours that might put them on risk for infection. Based on the S. haematobium infection prevalence determined in the annual cross-sectional surveys, study areas will be stratified in hotspots and low-risk areas. Hotspots will receive a combination of periodic MDA, snail control and behavior change interventions. Low-risk areas will receive targeted surveillance-response interventions, consisting of test-and-treat of high-risk groups, snail control in water bodies used by infected individuals, and health education of infected individuals.

What are the possible benefits and risks of participating?
The direct benefit from participation in the study is that participants will be informed about their S. haematobium infection status and will receive treatment with praziquantel if positive. The treatment can improve the general health status, including less pain, fatigue and weakness and thus improved school or working performance. Moreover, participating schools and shehia communities will benefit from the behaviour change interventions, including the implementation of laundry platforms and improved education about schistosomiasis prevention and transmission. Participating shehia communities will also benefit from snail control, which reduces the risk of S. haematobium transmission in the natural open water bodies of the targeted shehias.
For the participants, no risks are involved in producing a fresh urine sample. The questionnaires will include some questions that might be embarrassing, discomforting or too personal; however, participants can deny responding to these questions when they decide to participate.

Where is the study run from?
Swiss Tropical and Public Health Institute, Basel, Switzerland and Public Health Laboratory-Ivo de Carneri, Pemba, Tanzania

When is the study starting and how long is it expected to run for?
September 2019 to June 2024

Who is funding the study?
Swiss National Science Foundation (Switzerland)

Who is the main contact?
Dr Stefanie Knopp
s.knopp@swisstph.ch

Contact information

Type(s)
Scientific

Contact name
Dr Stefanie Knopp

ORCID ID
https://orcid.org/0000-0001-5707-7963

Contact details
Socinstrasse 57
Basel
Switzerland

4002
+41 (0)61 2848 727
s.knopp@swisstph.ch

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
21.01.2020 (Version 2.1)

Study information

Scientific Title
The last mile: novel tools and strategies for breaking schistosomiasis transmission

Acronym
Schistobreak

Study objectives
The study does not test a null hypothesis because the primary analysis will estimate a population parameter. The parameter of interest is the sensitivity of the risk-based surveillance system.
The sensitivity (and corresponding confidence intervals) is estimated as:
SE = number of infected persons detected by the surveillance system / total number of infected persons
whereby the total number of infected persons is calculated from the cross-sectional surveys as:
N_inf = Prevalence_school * N_pop-school + Prevalence_non-school * N_pop-non-school

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 23/10/2019, Ethics Committee Northwest and Central Switzerland (EKNZ) (Hebelstrasse 53, 4056 Basel, Switzerland; Tel:+41 (0)61 2681350; Email: eknz@bs.ch), ref: Project-ID: Req-2019-00951
2. Approved 13/12/2019, Zanzibar Health Research Ethical Committee (ZAHREC) (Ministry of Health Zanzibar, PO Box 236, Vuga Zanzibar; Tel: +255 (0)772 605560; Email: info@zahri.org), ref: NO.ZAHREC/03/PR/DEC/2019/12

Study design
Interventional surveillance study complemented by repeated cross-sectional surveys

Primary study design
Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied
Schistosoma haematobium infection

Interventions
The S. haematobium prevalence will be determined annually in cross-sectional surveys conducted in schools and communities of the study area. The baseline survey will be conducted in 2020, and follow-up surveys in 2021, 2022, and 2023. Depending on the S. haematobium prevalence, the study areas (shehias) will be stratified into hotspot or low-risk shehias and receive interventions accordingly for the year following the cross-sectional survey.

Inhabitants of hotspot shehias will receive mass drug administration (MDA) with praziquantel (40 mg/kg) as part of the routine interventions of the Neglected Tropical Diseases (NTD) Programme of the Zanzibar Ministry of Health (MoH) distributing praziquantel at least annually to the whole population of Zanzibar. Moreover, snail control using the molluscicide niclosamide will be carried out regularly in all natural waterbodies containing the intermediate host snails throughout the study years with the exception of the rainy season. Snail control will be carried out by experienced and trained research teams. Finally, behaviour change interventions containing interactive education in schools and communities using a pretested toolkit and safe laundry platforms will be implemented throughout the study years. Behaviour change activities will be carried out by experienced and trained research teams.

Inhabitants of low-risk shehias will not receive MDA. Here surveillance-response interventions will be carried out throughout the study years. Surveillance of high-risk groups will be done by a test-and-treat approach. Individuals infected with S. haematobium will receive a single dose of praziquantel (40 mg/kg) by staff of the research teams in collaboration with the Zanzibar NTD Programme. Additional response interventions will include snail control in infested water bodies of low-risk shehias and education of infected individuals on how to prevent S. haematobium transmission and infection.

Intervention Type
Mixed

Primary outcome(s)
The number of S. haematobium infected individuals detected and reported through the surveillance system divided by the number of positive individuals in the population as extrapolated from the cross-sectional surveys, i.e. the mean sensitivity of the surveillance-response system determined over 3 years. S. haematobium infections will be determined by the urine filtration method (detecting S. haematobium eggs in 10 ml urine) and reagent strip method (Hemastix; detecting microhaemturia in urine) applied on a single urine per participant in annual cross-sectional surveys (i.e. at baseline in 2020 and follow-up surveys in 2021, 2022, and 2023). For surveillance of high-risk groups the researchers will use the reagent strip method as a rapid test indicator for S. haematobium infections throughout the study years (2020 till 2023).

Key secondary outcome(s))
1. Performance parameters of the surveillance system:
1.1. Sensitivity of surveillance-response system for each study year (S. haematobium infection measured by the urine filtration method, by reagent strips and new rapid diagnostic tests once available; determined throughout the years during surveillance and in annual cross-sectional

surveys in 2020, 2021, 2022 and 2023)
1.2. Timeliness of case notification and reactive intervention throughout the study years (time from case notification by active and passive surveillance to reactive intervention; measured by comparing the dates of records pertaining to surveillance and response throughout the study years 2020 till 2023)
1.3. Acceptability of surveillance-response throughout the study years (feedback from study participants with regard to surveillance-response activities; annually measured by questionnaire interviews during cross-sectional surveys interviews in 2020, 2021, 2022 and 2023)
2. Impact of interventions in hotspots over time:
2.1. S. haematobium prevalence in annual cross-sectional surveys (S. haematobium egg absence /presence in 10 ml urine measured by urine filtration and microhaematuria absence/presence measured by reagent strips; annually measured during cross-sectional surveys in 2020, 2021, 2022 and 2023)
2.2. S. haematobium infection intensity in annual cross-sectional surveys (S. haematobium egg counts in 10 ml urine; measured by urine filtration; annually measured during cross-sectional surveys in 2020, 2021, 2022 and 2023)
3. Impact of reactive interventions in low-risk areas over time:
3.1. S. haematobium prevalence in annual cross-sectional surveys (S. haematobium egg absence /presence in 10 ml urine measured by urine filtration and microhaematuria absence/presence measured by reagent strips; annually measured during cross-sectional surveys in 2020, 2021, 2022 and 2023)
3.2. S. haematobium infection intensity in annual cross-sectional surveys (S. haematobium egg counts in 10 ml urine; measured by urine filtration; annually measured during cross-sectional surveys in 2020, 2021, 2022 and 2023)
4. Treatment coverage of MDA or test-and-treat in infected and healthy individuals:
4.1. Coverage and compliance with praziquantel treatment in the round of MDA preceding the cross-sectional survey in hotspot areas, determined in annual cross-sectional surveys (coverage = receiving praziquantel tablets during MDA, compliance = swallowing praziquantel tablets in the dose supplied during MDA; annually measured during cross-sectional surveys in 2020, 2021, 2022 and 2023)
4.2. Percentage of total shehia population treated by risk-based test-and-treat in low-risk areas throughout the study years (measured by records of test-and-treat activities throughout the study years 2020 till 2023)
5. Performance of diagnostic approaches:
5.1. Diagnostic sensitivity (percentage of true S. haematobium positive individuals, correctly diagnosed by the test under investigation in comparison with a reference test)
5.2. Diagnostic specificity (percentage of true S. haematobium negative individuals, correctly diagnosed by the test under investigation in comparison with a reference test)

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. All persons aged >3 years, living in the study shehias
2. Submitted informed consent form (ICF) signed by parent or legal guardian in case of participating children and adolescents, or signed by the participant in case of participating adults
3. One urine sample with sufficient volume to perform diagnostic tests provided

Participant type(s)

All

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
3 years

Upper age limit
110 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Children ≤3 years
2. Children, adolescents and adults not living in the study area
3. ICF not submitted or not signed by parent or legal guardian in case of participating children or adolescents or not signed by the participant in case of participating adults
4. No urine sample of sufficient volume to perform diagnostic tests provided

Date of first enrolment
15/05/2020

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
Tanzania

Sponsor information

Organisation
Swiss Tropical and Public Health Institute

ROR
https://ror.org/03adhka07

Funder(s)

Funder type
Research organisation

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are and will be stored in a publicly available repository once related manuscripts are published; Repository (Name): Zenodo (https://zenodo.org/).

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/07/2024	03/07/2024	Yes	No
Results article		02/06/2025	05/06/2025	Yes	No
Results article		30/09/2025	01/10/2025	Yes	No
Results article		17/06/2024	30/12/2025	Yes	No
Results article		03/02/2026	04/02/2026	Yes	No
Protocol article		30/09/2021	30/08/2022	Yes	No

Dataset		02/05/2025	30/12/2025	No	No
Dataset		16/08/2022	30/12/2025	No	No
Dataset		22/01/2022	30/12/2025	No	No
Dataset		26/11/2024	30/12/2025	No	No
Dataset		13/11/2024	30/12/2025	No	No
Dataset		17/06/2024	30/12/2025	No	No
Other publications	Evaluation of tablet-based fine-scale mapping approach	15/01/2022	17/01/2022	Yes	No
Other publications	Baseline parasite infection prevalence and intermediate host abundance	16/08/2022	30/08/2022	Yes	No
Other publications		13/11/2024	20/11/2024	Yes	No
Other publications		26/11/2024	28/11/2024	Yes	No